# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 19-1434V UNPUBLISHED

BRIANNA ZABEK,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 20, 2022

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination; Statutory Six Month Requirement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Felicia Langel, U.S. Department of Justice, Washington, DC, for Respondent.

# FINDINGS OF FACT<sup>1</sup>

On September 18, 2019, Brianna Zabek filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine she received on September 24, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

<sup>&</sup>lt;sup>1</sup> Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that Petitioner's September 24, 2017 flu vaccine was likely administered to her right shoulder, and that she suffered the residual effects of her injury for more than six months.

## I. Relevant Procedural History

Ms. Zabek filed her petition and medical record exhibits on September 18, 2019. (ECF No. 1). Fourteen months later, Respondent filed a status report stating that he intended to continue to defend the case and requested that a deadline be set for the Rule 4(c) report. (ECF No. 17).

On January 28, 2021, Respondent filed his report pursuant to Vaccine Rule 4(c) contesting entitlement for several reasons. (ECF No. 18). First, Respondent noted that Petitioner's vaccination record states that Ms. Zabek received the flu vaccine on September 18, 2019, to her left shoulder, not her right shoulder as the petition alleges. *Id.* at 4. Respondent argues that although Petitioner states she received the vaccine her right shoulder and sought treatment for her right shoulder, her statements should not "outweigh the contemporaneous medical records that clearly document vaccine administration to her left arm." *Id.* 

Second, Respondent argues that Petitioner has not shown that the symptoms from her injury have lasted for more than six months. Rule 4(c) Report at 6. Respondent states Ms. Zabek was discharged from physical therapy on February 5, 2018, four and a half months after her vaccination, and reported feeling "90% better compared to when she started." *Id.* Although Petitioner was subsequently seen for two more visits, she did not have any complaints about her shoulder. *Id.* at 6-7. Thus, Respondent argues that Petitioner's vaccination shoulder injury did not persist for the requisite six months after vaccination to establish the severity requirement under 42 U.S.C. § 300aa-11(c)(D)(i).

The parties have briefed the issues in dispute ("Motion" and "Response") and have requested that I issue a ruling. My findings are presented below.

#### II. Issue

At issue is (1) whether Petitioner received the vaccination alleged as causal in her right shoulder, and (2) whether Petitioner continued to suffer the residual effects of the SIRVA for more than six months. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); Section 11(c)(1)(D)(i) (statutory six-month requirement).

#### III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

#### IV. Finding of Fact

I make the findings after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4(c) report, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Petitioner's medical history is unremarkable for any shoulder symptoms or injuries prior to the date of vaccination. See generally Ex. 3.
- Petitioner received a flu vaccine on September 24, 2017, at CVS Pharmacy located in Woodstock, Georgia. Ex. 1 at 6-7. The screenshot of the vaccination record states that the site of vaccination is the left shoulder. *Id*. at 7.
- Petitioner provided a time-stamped photograph, dated September 25, 2017, one day after vaccination, showing her right shoulder. Ex. 2(a-b). In her affidavit, Petitioner states that she took the photograph to document the bruise at the injection site. Ex. 6 at 1.
- Eleven days later on October 5, 2017, Petitioner presented to her primary care physician, Dr. Christopher Parman, complaining of right shoulder pain. Ex. 3 at 51. Dr. Parman's notes state: "36 year old female presents with c/o shoulder pain right, laterally, localized in the shoulder. c/o direct trauma flu shot. c/o tingling / numbness... Patient states she had a flu vaccine on about a week and a half ago and ever[] since her right shoulder has been hurting. She believes the tech administered it to[o] high, close to her joint." *Id*.
- One week later on October 12, 2017, Petitioner presented to Benchmark Rehab Partners physical therapy for an initial evaluation. Ex. 4 at 82. The evaluation record states "Patient presents to skilled PT with primary

complaints of R shoulder pain and weakness. She reports her pain started a couple of weeks ago, after getting the flu shot on 9/25. Patient reports while receiving the flu shot it seemed to be more painful than usual and seemed as though the person who administered the shot put it higher than usual and took longer to do so. Patient reports her pain and weakness started the day following shot. Her pain was subsiding so she worked out about a week later, resulting in marked increased in pain again. Patient has since discontinued exercise and R shoulder has gotten progressively better over the last week again." *Id*. Petitioner was scheduled to attend physical therapy twice a week for four weeks. *Id*. at 86.

- From October 2017 to February 2018, Petitioner attended 19 physical therapy sessions. See Ex. 4. During that time, Ms. Zabek rated her pain from an 8 out of 10 at its worst, to a 0 during her final session. Ex. 4 at 21. She was discharged on February 5, 2018, with a "significant improvement in R shoulder ROM, strength, endurance, and coordination," although she still experienced soreness following gym activities. Id. at 11.
- In February 2018, Petitioner averred that she requested a discharge from physical therapy when she believed she could "make progress on [her] own." Ex. 6 at 1. She stated that she still had pain with some movements and diminished strength. *Id*.
- Approximately eight months later on October 10, 2018, during a follow up exam for IBS, Petitioner indicated that she wanted to get the flu vaccine but was concerned about getting the vaccine due to her previous shoulder injury. Ex. 3 at 33. Dr. Parman noted "c/o shoulder pain right, anterior s/p influenza vaccine in Sept. 2017. Her severe pain lasted about 2 months after the vaccine. She did physical therapy last year and her pain improved, but still present. P[atien]t c[omplains] o[f] intermittent pain in the right shoulder with certain motions such as lifting in front or across. Planks can hurt. She works out with weights and this doesn't always bother her... physical therapy in the past..." Ex. 3 at 33. On examination, Petitioner exhibited palpation and tenderness on the bicipital tendon, mild tenderness on the subacromial bursa. She had pain with flexion at the shoulder and mild pain with biceps flexion. The impingement sign of the right shoulder was positive. *Id.* at 35. Petitioner was advised to modify her activities and to continue with strengthening exercises. *Id.*

#### A. Site of Vaccination

After a review of the record, it is clear that Petitioner has met her burden of proving, by preponderant evidence, that she received the September 23, 2017, in her right shoulder. Just one day following vaccination, Ms. Zabek photographed her right shoulder area, noting the pain and bruising that the flu vaccine caused to her upper right deltoid. Ex. 2. The photo of the shoulder appears authentic and has not otherwise been undermined by Respondent.

Petitioner also sought treatment close in time to her injury - visiting her primary care physician just 11 days post-vaccination. In every record of treatment for her shoulder following September 2017, Ms. Zabek consistently reported right shoulder pain, which she attributed to that vaccination.

Admittedly, the vaccination record - a screenshot of a computer database used by CVS Pharmacy — indicates a left-side vaccination. But (relying on my experience resolving SPU SIRVA cases (more than 1,200 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled in chambers) I find it is not unusual for the information regarding site of vaccination to be incorrect.<sup>3</sup> In many instances, the purported record is created prior to vaccination, and is not updated thereafter - even if the vaccine is then administered in the opposing arm.<sup>4</sup> Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply *because* they come first — and in fact the nature of their creation provides some basis for not accepting them at face value.

Where medical records are clear, consistent, and complete, I am to afford those records substantial weight. However, those medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Blutstein,* 1998 WL 408611, at \*5. The inconsistencies that exist regarding the arm of vaccination in Ms. Zabek's case dictates that I consider the record as a whole in making

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<sup>&</sup>lt;sup>3</sup> See, e.g., Arnold v. Sec'y of Health & Hum. Servs., No. 20-1038V 2021 WL 2908519, at \*4 (Fed. CL. Spec. Mstr. June 9, 2021); Syed v. Sec'y of Health & Hum. Servs., No. 19-1364V, 2021 WL 2229829, at \*4-5 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); Ruddy v. Sec'y of Health & Hum. Servs., No 19-1998V, 2021 WL 1291777, at \*5 (Fed. Cl. Spec. Mstr. Mar. 5, 2021); Desai v. Sec'y of Health & Hum. Servs., No 14-0811V, 2020 WL 4919777, at \*14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Hum. Servs., No. 18-0559V, 2020 WL 1870268, at \*5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Hum. Servs., No. 17-0990V, 2018 WL 6718629, at \*4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

<sup>&</sup>lt;sup>4</sup> In a recent ruling by another special master, the pharmacist who had administered the relevant vaccination actually testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, based upon the assumption that most vaccinees are right-handed. *Mezzacapo v. Sec'y of Health & Hum. Servs.*, No. 18-1977V, 2021 WL 1940435, at \*4 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

my determination. While the vaccination record states that the flu vaccine was administered to Petitioner's left arm, *all* other medical records all state that Ms. Zabek received the vaccine to her right shoulder.

I thus find that there is sufficient evidence that the vaccine was likely administered to Petitioner's right shoulder to overcome the contrary administration record. The subsequent treatment records gain strength as well as given their temporal proximity to the date of vaccination.

#### B. Six Month Sequela

In this case, to satisfy the Vaccine Act's severity requirement Petitioner must show that she suffered symptoms of her alleged SIRVA beyond March 24, 2018. Respondent argues that Petitioner has failed to meet her burden on this point. In support, Respondent notes that Ms. Zabek was discharged from physical therapy on February 5, 2018, four and a half months after vaccination. Response at 10. At that time, the records indicated that Petitioner reported feeling "90% better compared to when she started." *Id*.

Petitioner was subsequently seen by her PCP in May and September 2018, where the records make no mention of shoulder pain. In October 2018, eight months after discharge from physical therapy, Ms. Zabek again reported right shoulder pain. Ex. 3 at 33-35. Respondent thus argues that there "is no objective evidence of a shoulder injury during this visit" because the observations made by Petitioner's doctor "relate primarily to petitioner's subjective reporting of pain during various parts of the examination." Response at 11. Respondent also notes that Petitioner had full strength in her right shoulder during the examination and performed exercises "that would have been difficult if she was experiencing significant or persistent shoulder pain." *Id*.

Respondent's argument on this issue is unpersuasive. This is particularly due to the fact that, in effect, Respondent requests that I do what he previously argued I should not do: ignore the information contained in the contemporaneously-created medical records. Thus, during Ms. Zabek's visit with her PCP on October 10, 2018, Dr. Parman conducted a physical examination of Petitioner's right shoulder during which he noted "palpation: + tenderness on bicipital tendon, mild tenderness on subacromial bursa." Ex. 3 at 35. He conducted a shoulder impingement test that was positive. These are not just subjective reports by Petitioner. Dr. Parman conducted an examination designed to yield objective results. There is absolutely no indication that these objective findings were based solely on Petitioner's reports. She was in-person and present for the physical examination.

Moreover, Respondent seems to suggest that between the time Ms. Zabek was discharged in February 2018, and when she was seen again in October 2018 complaining of shoulder pain, that she may have injured her shoulder performing gym exercises or some other intervening event. But there is no evidence in the record to support that inference. Ms. Zabek had no shoulder injuries or symptoms prior to vaccination – a point that Respondent does not dispute. She began exhibiting shoulder pain and symptoms very shortly after vaccination, which is clearly documented in the records. Even though Petitioner ceased physical therapy based on the optimistic assumption that she was doing better, the record establishes that her shoulder symptoms were not completely resolved. Indeed, Respondent acknowledges this, in citing to Petitioner's statement that she felt only "90%" improved on discharge.

Overall, it is speculative to propose that the clear treatment gap contained within it some kind of intervening cause of subsequent pain. That gap is not insubstantial, but also not long enough to give such speculation weight. Of course, this does not mean that gap has no bearing on this case – to the contrary, it will be factored when computing damages. But it does not prohibit the conclusion that Petitioner's SIRVA had *not* fully resolved within six months of vaccination.

Accordingly, I find there is preponderant evidence to both establish that the vaccination alleged as causal in this case was administered to Petitioner in the right deltoid on September 24, 2017, and that Petitioner suffered the residual effects of her injury for more than six months.

#### V. Scheduling Order

Given my findings of fact, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

## Accordingly, the following is ORDERED:

- (1) By Monday, August 26, 2022, Petitioner shall file all updated medical records.
- (2) Respondent shall file, by no later than <u>Monday</u>, <u>September 19</u>, <u>2022</u>, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

# IT IS SO ORDERED.

# s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master